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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/674,277

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Dominique Therese Marie Frechon

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09/27/2004

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,277

Applicant(s)

FRECHON ET AL.

Examiner

Patricia A. Duffy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 20-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

The new claims as set forth in the amendment of 5-12-04 are not interpretable with respect to the correction to the specification and assertion that SEQ ID NOS:3-20 are fragments of SEQ ID NO:1 and SEQ ID NOS:21-27 are fragments of SEQ ID NO:2. Applicants' new claims are inconsistent and contradict this assertion. The lack of unity set forth herein depicts the claims as specifically recited in view of the claimed dependency and not Applicants assertion. It is noted that claims 24 and 25 therefore appear as dependent from the recited sequence in the respective independent claim.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 20, 23, and 25, drawn to the first appearing technical feature of an isolated nucleic acid consisting of SEQ ID NO:1 or SEQ ID NO:2 or their complementary sequences or a fragment of SEQ ID NO:2 or a sequence derived from SEQ ID NO:2 by mutation, insertion, deletion and/or substitution of one or more bases.

Group 2, claims 21, 22, 24 drawn to fragments and derivatives of SEQ ID NO:1, representing the second technical feature.

Group 3, claims 26, 55, 56 and, 57, drawn to combinations of primer pairs or pairs of fragments and kits comprising these, representing the third technical feature.

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Group 4, claims 27 and 29 drawn to a particularly deposited plasmid and host cell containing the plasmid, the fourth technical feature.

Group 5, claims 28 and 30, drawn to a particularly deposited plasmid and host cell containing the plasmid, the fifth technical feature.

Group 6, claims 31-41 and 59 drawn to the first method of use of the first appearing method of the technical feature of Group 1, fragments of SEQ ID NO:2.

Group 7, claims 42-54 and 60 drawn to the first method of use of the second appearing technical feature of Group 2, fragments of SEQ ID NO:1.

The inventions listed as Groups 1-7 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical features of Groups 1-7 are set forth *supra*. Group 1 is anticipated by Makino et al , (DNA Research, 541:1-9, Feb 28, 1998). Makino et al teach the isolation and purification of a plasmid that inherently contains a sequence that is 98.7% identical as compared to SEQ ID NO:2 and as such meets the limitation of derived sequence of SEQ ID NO:2 by mutation, insertion, deletion, and/or substitution and would hybridize to SEQ ID NO:2 under highly stringent conditions. Further, the fragments are anticipated by Sigma Chemical Company that teaches monophosphorylated nucleic acid bases (AMP), the smallest fragment of any nucleic acid sequence. Applicants argued that the sequence was not publicly available, this is not persuasive, the sequence is inherent to the isolated plasmid and therefore the claim as drafted is anticipated. Additionally, the claim as it now recites consisting of SEQ ID NO:1 lacks unity of invention with claim 21 or any fragment thereof, because claim 21 does not consist of SEQ ID NO:1, but is something different and therefore claim 21 does not

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share the same corresponding technical feature of Group 1. The first appearing technical feature of Group 1 is anticipated by the art and does not share the corresponding technical feature of Groups 2-5 as defined *supra*. Because the technical feature of Group 1 is anticipated, the technical feature of Group 1 is not "special" in that it does not define a technical feature that defines the invention over the art as set forth in PCT Rule 13.2 and therefore the associated method of use of the first appearing technical feature (Group 6) lacks unity of invention with Group 1. The method of Group 7 (i.e. claim 42) does not share the corresponding technical feature of Group 1 and therefore by definition lacks unity of invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group 1, any of the claimed fragments of SEQ ID NO:2 (see list of recited fragments in claims 23 and 25).

Group 2, any of the claimed fragments of SEQ ID NO:1 (see list of recited fragments in claims 22 and 24).

Group 3, any single pair of the recited primer pairs (see list of recited pairs of fragments in claims 26, 55-57).

Group 6, any method of use of any the claimed fragments of SEQ ID NO:2 or a specific combination thereof.

Group 7, any method of use of the claimed fragments of SEQ ID NO:1 or a specific combination thereof.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently

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added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 20, 21, 31 and 42.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: because the technical feature of Group 1 that includes the generic fragment language anticipated as set forth above, and therefore do not define a novel contribution over the prior art. Because claim 20 of Group 1 is anticipated and the generic fragment of SEQ ID NO:2 is anticipated, the claimed species of fragments lack unity of invention because they fail to share a corresponding special technical feature or similar structure that defines them over the art. The species are not linked by a corresponding technical feature that is "special" within the meaning of Rule 13.2.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia A. Duffy
Patricia A. Duffy

Primary Examiner

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